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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/830,071 | 04/23/2004 | Kishore M. Gadde | 1579-904 | 7687 |

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| EXAMINER | |
|---|---|
| JONES, DWAYNE C | |
| **ART UNIT** | **PAPER NUMBER** |
| 1614 | |

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/830,071 | GADDE ET AL. | |
| | Examiner | Art Unit | |
| | Dwayne C. Jones | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27MAR2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *18-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Claims*

1. Claims 18-43 are pending.

2. Claims 18-43 are rejected.

### *Response to Arguments*

3. Applicant's arguments filed March 27, 2006 have been fully considered but they are not persuasive. Applicants present the following arguments. Applicants argue that the prior art references of record do not teach of weight loss that is "significant and sustained." Applicants also elected to hold the pending double patenting rejections in abeyance until the prosecution of the present application has progressed.

4. However, the fact remains that the prior art of record does in fact teach the skilled artisan of decreasing weight loss (as in Ayala, R.) with zonisamide; treating obesity with the administration of topiramate (as taught by Shank). In addition, Coffin et al. teach of the combined administration of bupropion along with zonisamide. However, since the parameters phrase of "significant and sustained" are unclear, the metes and bounds of the claim are in fact meet by the prior art references of record.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 18-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayala, R. in view of Shank of U.S. Patent No. 6,071,537 both in view of Anderson et al. of U.S. Patent No. 6,437,147.

9. Ayala, R. teach of the administration of zonisamide is effective in decreasing weight loss in patients, (see abstract). Shank teaches of treating obesity with the administration of compounds of formula I, including topiramate. The prior art reference of Anderson et al. specifically teaches of the administration of bupropion for the treatment of obesity, (see column 26, lines 47-49). "It is prima facie obvious to combine

two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). For these reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity. Moreover, the skilled artisan would have additionally been motivated to treat related ailments where the eating disorders are manifested, such as with bulimia nervosa or anorexia nervosa, due to the fact that eating disorders, for instance bulimia nervosa or anorexia nervosa, obviously may be treated with pharmaceutical agents that control or suppress the appetite of an individual in need thereof, which would assist the individual by inter alia by controlling weight gain with these known compounds, such as zonisamide and topiramate. Accordingly, it would logically follow to reduce the risk of an individual from developing diabetes can be achieved by treating obesity as clearly taught by the prior art references of Ayala, R. or Shank of U.S. Patent No. 6,071,537 both in view of Anderson et al.

10. Claims 18-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffin et al. of US Patent Application Publication 2001/0025038.

11. It is first pointed out that the prior art reference of Coffin et al. is directed to a method for reducing cravings to food **or** an addictive substance with the administration of bupropion and zonisamide. This claim of Coffin et al. is written in the alternative, which does provide the skilled artisan with the necessary motivation and guidance to

treat obesity or reduce weight gain in an individual in need thereof by reducing cravings for food to an individual in need thereof.

12. Accordingly, Coffin et al. teach of methods of reducing food cravings in mammals with the combined administration of antidepressant drugs, in particular bupropion, and anticonvulsant drugs, namely zonisamide, (see page 5 paragraphs 72, 76 and 78). In addition, Coffin et al. teach that these compounds may co-administered simultaneously or sequentially as well as being available in oral dosage forms, such as capsules and tablets, (see paragraph 84). Because the prior art reference of Coffin et al. teach of methods of reducing food cravings in mammals with the combined administration of antidepressant drugs, in particular bupropion, and anticonvulsant drugs, namely zonisamide, the prior art reference of Coffin et al. inherently teaches of the single administration of zonisamide for the very same method of reducing food cravings in mammals. From these teachings, one having ordinary skill in the art is provided with the necessary teachings and motivation to employ zonisamide (see paragraphs 72, 76, and 78) and even specifically with bupropion (see claim 10) with Coffin et al. Accordingly, it would logically follow to reduce the risk of an individual from developing diabetes can be achieved by treating obesity as clearly taught by Coffin et al.

***Obviousness-type Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. The provisional rejection of claims 18-43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-10, 13-19 of copending Application No. 10/440,404 is maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application No. 10/440,404 teach of treating obesity and hypertension (and diabetes or dyslipidaemia) with the administration of zonisamide or topiramate along with bupropion. For these reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity. Moreover, the skilled artisan would have additionally been motivated to treat related ailments where the eating disorders are manifested, such as with bulimia nervosa or anorexia nervosa, due to the fact that eating disorders, for instance bulimia nervosa or anorexia nervosa, obviously may be treated with pharmaceutical agents that control or suppress the appetite of an individual in need thereof, which would assist the individual by inter alia by controlling weight gain with these known compounds, such as zonisamide and topiramate.

15. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. The provisional rejection of claims 18-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-34 of copending Application No. 11/058,981 is maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application No. 11/058,981 teach of treating obesity and hypertension (and diabetes or dyslipidaemia) with the administration of zonisamide or topiramate along with bupropion. For these reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity.

17. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. The provisional rejection of claims 18-43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-38 of copending Application No. 11/059,027. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application No. 11/059,027 teach of treating obesity and hypertension (and diabetes or dyslipidaemia) with the administration of zonisamide or topiramate along with bupropion as well as its pharmacological metabolites. For these reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity. Moreover, it is established that metabolites or pharmacological agents are inherent with the administration of the pharmacological agent.

19. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. The provisional rejection of claims 18-43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/034,316. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and copending Application No. 11/034,316 teach of treating weight gain with the administration of zonisamide or topiramate along with bupropion as well as its pharmacological metabolites. For these reasons, the skilled artisan would have been motivated to combine these well-known pharmaceuticals for the treatment of the very same ailment of obesity. Moreover, it is established that metabolites or pharmacological agents are inherent with the administration of the pharmacological agent.

21. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## *Conclusion*

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, may be reached at (571) 272-0718. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see http://pair-direct.uspto.gov. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

DWAYNE JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
May 16, 2006